UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

ADAM STREETER, an individual, Plaintiff, vs. ELI LILLY AND COMPANY, a corporation, Defendant.	Case No.: 3:14-cv-00555-wmc **FIRST CORRECTED AMENDED COMPLAINT**

COMES NOW Plaintiff, Adam Streeter, by and through undersigned counsel, and for his cause of action files this Complaint for damages against the above-named Defendant alleging the following:

INTRODUCTION

1. This is a civil action for products liability alleging personal injuries and damages, including serious withdrawal symptoms, suffered by Plaintiff Adam Streeter as a direct and proximate result of his ingestion and cessation of the prescription drug, Cymbalta (duloxetine), which is manufactured, marketed, and sold by Defendant Eli Lilly and Company (hereinafter, "Defendant" or "Lilly"). This civil action alleges that Plaintiff's personal injuries and damages were suffered as a result of Lilly's failure to adequately warn physicians and consumers about the frequency, severity, and/or duration of symptoms associated with discontinuation of Cymbalta (throughout, interchangeably "discontinuation" or "withdrawal" "symptoms" or "syndrome"), and for failure to design Cymbalta in a way that would allow Plaintiff to safely and effectively taper from taking Cymbalta. Plaintiff's claims sound in negligence, strict product liability, fraud, concealment, and breach of warranty.

PARTIES

2. Plaintiff Adam Streeter (hereinafter, "Plaintiff") is, and at all times relevant to this

Complaint was, a citizen of the State of Minnesota, County of Hennepin from at least Summer 2006 until Fall 2009, and a citizen of the State of Wisconsin, County of Marathon from Fall 2009 to the present.

3. Defendant Eli Lilly and Company is, and at all times relevant to this Complaint was, an Indiana corporation with its headquarters in Indianapolis, Indiana. Lilly is a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, marketing and sale of numerous pharmaceutical products, including Cymbalta, a prescription antidepressant drug.

JURISDICTION AND VENUE

4. This Court has personal jurisdiction over Lilly insofar as Lilly is authorized and licensed to conduct business in Wisconsin, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

5. Furthermore, Lilly has caused tortious injury by acts and omissions in this judicial district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

6. This Court has subject matter jurisdiction in the form of diversity jurisdiction, pursuant to 28 U.S.C.A. § 1332, in that there is a complete diversity of citizenship between Plaintiff and Defendant and the amount in controversy exceeds $75,000.00.

7. Venue is proper pursuant to 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

8. Lilly is one of the largest pharmaceutical companies in the world with annual

revenues exceeding $20 billion. From 2004 through 2014, a substantial portion of Lilly's revenue was derived from its drug Cymbalta, whose 2009 annual sales exceeded $3 billion domestically and $5 billion worldwide.

9. Lilly has enjoyed considerable financial success from manufacturing and selling prescription drugs for the treatment of clinical depression, including the popular antidepressant Prozac (generically known as fluoxetine). Lilly launched Prozac in 1988 touting it as the first "Selective Serotonin Reuptake Inhibitor" ("SSRI"). SSRIs are a class of antidepressant drugs that were promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. It has been theorized that reduced levels of serotonin cause depression; however, recent studies have undermined this theory. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001.

10. In 2001, Lilly needed to fill the void left behind by Prozac's patent expiration, and so it sought approval by the Food and Drug Administration ("FDA") for its next antidepressant, Cymbalta. Unlike Prozac, Cymbalta is a "Serotonin-Norepinephrine Reuptake Inhibitor" ("SNRI"), which Lilly promoted as increasing the brain chemicals serotonin and norepinephrine in the synaptic clefts between the neurons in the brain. Lilly and other SNRI manufacturers admit that the precise mechanism of action is not clear, however, they have promoted the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

11. In 2003, the FDA initially rejected Lilly's application to approve Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

12. Eventually, in 2004, manufacturing issues were resolved and the FDA approved Cymbalta with a liver toxicity warning included in the prescribing information. The drug was approved for Major Depressive Disorder ("MDD"). In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and in 2008 for treatment of fibromyalgia.

13. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending hundreds of millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff, through all major media channels, including internet, print and television. In addition, Lilly has promoted Cymbalta to the medical community by utilizing its well-organized army of sales representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

14. Lilly's promotional campaigns have continuously failed to provide adequate instructions to users and health care professionals for stopping Cymbalta and have failed to include adequate warnings that fully and accurately inform users and health care professionals about the frequency, severity, and/or duration of Cymbalta withdrawal and that Cymbalta is not designed in such a way that would easily allow for a gradual tapering off of the drug.

15. Withdrawal symptoms are not connected to a patient's underlying condition but rather are the body's physical reactions to the drug leaving the system. While many SSRIs and SNRIs can cause withdrawal symptoms, the initiation, frequency, and severity of withdrawal symptoms correlate to a drug's half-life. The half-life of a drug is the time it takes for the

concentration of the drug in the body to be reduced by half. This information is one of the basic pharmacokinetic properties of a drug and is known to researchers developing the drug. Cymbalta's half-life is approximately 12 hours, which is one of the shortest half-lives of any of the SSRIs and SNRIs. In contrast, the half-life of Prozac is seven days. The shorter the half-life, the faster the body eliminates the drug from the system, thus creating a higher risk of withdrawal symptoms. Because Cymbalta's half-life is less than one day and Cymbalta is generally administered once daily, it is possible for users of Cymbalta to experience withdrawal symptoms after simply forgetting to take one dose. This also means that users cannot safely taper off of the drug by reducing their frequency of dosing (from once every 24 hours to every 48 hours, etc.); the short half-life results in withdrawal-inducing low levels of the drug too quickly.

16. Despite Lilly's awareness of Cymbalta's half-life and the correlation between a short half-life and withdrawal risk, Lilly did not include any cross-references between the Pharmacokinetics section of the label and either the Precautions section or the Dosage and Use section. In fact, rather than drawing attention to the potential consequences of Cymbalta's extremely short half-life, Lilly misleadingly referenced all other SSRIs and SNRIs, as if Cymbalta could be expected to pose a similar risk of withdrawal as all other drugs of its class generally:

> During marketing of other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional liability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

[2004 Cymbalta Label.] The extremely short half-life of Cymbalta should have alerted Lilly to the fact that the risk of Cymbalta withdrawal would be more frequent than that experienced with

other SSRIs and SNRIs. Further, Lilly should have recognized that doses in increments of less than 20 mg—the smallest dose available—would be necessary to allow users to gradually taper off Cymbalta to avoid or mitigate withdrawal symptoms.

17. Lilly should have been aware of the significance of antidepressant withdrawal, because Lilly had previously researched and publicized the issue in connection with its antidepressant Prozac. Because Prozac has an extremely long half-life relative to other antidepressants, the length of time it takes for a person's body to fully eliminate Prozac from the system provides a built-in gradual tapering of sorts, so that withdrawal symptoms from Prozac are relatively infrequent. Prozac's main competitors in the 1990s, Zoloft and Paxil, had shorter half-lives, and Lilly engineered a campaign to differentiate Prozac from its competitors on this basis, funding clinical studies of antidepressant withdrawal and coining the term "antidepressant discontinuation syndrome."

18. Researchers, including Lilly's own consultants, have postulated that as SSRIs and SNRIs block the reuptake of serotonin and norepinephrine, structural changes in the brain occur such that production of these neurotransmitters is reduced. These changes in the brain's architecture may contribute to withdrawal symptoms, as a patient is, upon cessation of the drug, left not only with the absence of the drug but also structural changes in the brain that remain for some time even after the drug has fully washed out of the person's system. Because of the short half-life of Cymbalta, the brain has even less time to adjust to the cessation of Cymbalta treatment. Despite Lilly's knowledge of this phenomenon, Lilly did not include in Cymbalta's label or promotional materials any information regarding the increased risk of withdrawal due to structural changes in the brain exacerbated by Cymbalta's short half-life.

19. In 2004, when Cymbalta was introduced in the United States market, Lilly's

physician labeling (United States Package Insert, or "USPI") for Cymbalta stated the following with respect to discontinuation or withdrawal symptoms:

> Discontinuation of Treatment with Cymbalta – Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo-controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate **greater than or equal to 2%** and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, paresthesia, vomiting, irritability, and nightmare.

(emphasis added). Cymbalta's label also provided the following instructions for stopping Cymbalta:

> A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Id.

20. In 2007, Lilly changed the discontinuation precaution section of the USPI to state that symptoms occurred in Cymbalta users at a rate of "**greater than or equal to 1%**" (emphasis added).

21. By the time of the 2011 iteration of the USPI, Lilly had changed the language to state that these symptoms occurred at "**1% or greater**" (emphasis added).

22. In addition to using the euphemistic term "discontinuation" in both its USPI and patient Medication Guide to describe Cymbalta's withdrawal symptoms, the label did not accurately reflect that a significant percentage of Cymbalta users suffered from withdrawal symptoms. Rather, the warnings suggested that Cymbalta withdrawal was rare, occurring at a rate of approximately only 1% or 2%.

23. To the contrary, according to a January 2005 article published in the Journal of Affective Disorders, Lilly's Cymbalta clinical trials showed that, at a minimum, between

44.3% and 50% of Cymbalta patients suffered from "discontinuation" side effects. David G. Perahia *et al.*, Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder, 89 JOURNAL OF AFFECTIVE DISORDERS 207 (2005). The article also noted that the withdrawal symptom data compiled during Lilly's clinical trials was gathered from "spontaneous reports" of symptoms (patients volunteering symptoms) and not using the more accurate "symptom checklist." The authors acknowledged that use of a symptom checklist would likely produce even higher incidence rates of withdrawal symptoms.

24. Lilly has never disclosed this critical data in its USPI or its patient Medication Guide in the United States. In comparison, Lilly's European label disclosed that withdrawal symptoms occur in approximately 45% of patients upon discontinuation of Cymbalta. Instead of disclosing the incidence rate for discontinuation or withdrawal syndrome as an aggregate constellation of symptoms in the United States, Lilly's USPI has always provided merely a "frequency threshold" (or 1% or 2%) for individual symptoms, misleadingly suggesting that Cymbalta withdrawal syndrome is rare or infrequent.

25. Moreover, Lilly's clinical trials showed that, overall, between 9.6% and 17.2% of Cymbalta users suffered severe withdrawal symptoms, yet Lilly has never informed United States physicians or patients of that risk.

26. Cymbalta's withdrawal side effects include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures and vertigo. When patients try to stop taking Cymbalta, the symptoms can be severe enough to force them to start taking Cymbalta again, not to treat their underlying condition, but simply to stop the withdrawal symptoms. Patients thus become prisoners to Cymbalta, and Lilly financially

benefits by having a legion of physically dependent, long-term users of Cymbalta.

27. Notwithstanding Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly did not provide adequate instructions to users and physicians for stopping Cymbalta or warn users and physicians about the frequency, severity, and/or duration of the withdrawal symptoms.

28. Instead, in its product labeling, marketing and advertising, and in information made available to consumers and physicians, Lilly reported a far lower risk, downplayed any difference in the withdrawal risk for Cymbalta as compared to other similar antidepressants, and affirmatively misled the consuming patient population and mischaracterized the drug's risk profile.

29. Lilly's misleading direct-to-consumer promotional campaigns and its failure to adequately warn users and physicians about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms have paid off financially for Lilly. Prior to its patent expiration in December 2013, Cymbalta became a "blockbuster" drug with over $3 billion dollars in annual U.S. sales. In the past few years, Cymbalta has been the most profitable or second most profitable drug in Lilly's product line. Lilly had the knowledge, the means and the duty to provide adequate warnings regarding Cymbalta's common and severe withdrawal and dependency side effects as well as a duty to honestly portray the safety of Cymbalta. Lilly could have relayed these warnings through the same means it utilized to advertise its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements and sales representatives.

30. Additionally, although Lilly recommended "gradual reduction," it provided no information as to what that might mean for patients taking Cymbalta and their physicians. Lilly

did not, for example, provide any information regarding the recommended time period, as it did in its European Cymbalta label, which stated, "It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of *no less than 2 weeks*[.]" 2014 Cymbalta European Medicines Agency Label (emphasis added). Lilly also did not, for example, recommend dosing increments to follow when reducing the dose.

31. And, even though Lilly advised that the reduction in dose may be done at "a more gradual rate" if "intolerable" symptoms occur, Lilly failed to warn users and physicians that the design of Cymbalta makes it impossible for "a more gradual rate" to be achieved other than 10 mg increments and that no "gradual reduction" can take place below 20 mg, due to the design of Cymbalta capsules.

32. As Lilly was fully aware of the issue of antidepressant withdrawal and of Cymbalta's elevated withdrawal risk, Lilly should not only have included a strong warning to physicians and patients, but it should have also originally designed the drug in such a way that would easily allow for a gradual tapering off of the drug. Other SSRIs and SNRIs are available as scored tablets that can be halved and quartered with relative ease, or are available in liquid form which can be measured and dispensed in small increments. In contrast, Cymbalta is manufactured as a delayed-release capsule filled with tiny beads. The smallest dose in which Cymbalta is available is 20 mg. Cymbalta's label and Medication Guide instruct physicians and patients that the capsule "should be swallowed whole and should not be chewed or crushed, nor should the capsule be opened and its contents be sprinkled on food or mixed with liquids." Thus, unlike other SSRIs and SNRIs, the design of Cymbalta's delivery and dosing system prevent its smallest available dose of 20 mg from being incrementally reduced by users and physicians to help avoid or mitigate withdrawal symptoms. As a result, Cymbalta's design raised additional withdrawal

risk that was not warned about.

33. Falsely reassured by the misleading and deceptive manner in which Lilly reported Cymbalta's withdrawal risk, physicians, including Plaintiff's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate instructions for stopping Cymbalta and without adequate warnings that fully and accurately inform them about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms and that the ability to gradually taper was restricted because of Cymbalta's design.

34. On or around August 10, 2006, Plaintiff was prescribed Cymbalta by his physician, for treatment of depression and fibromyalgia. Fibromyalgia is a long-term condition of chronic muscle, joint, and tendon pain throughout the body.

35. On or around January 17, 2012 Plaintiff was concerned with the effects he experienced if he was late or missed a dose of Cymbalta. Under the care and supervision of his physician, Plaintiff elected to taper off of Cymbalta.

36. Plaintiff reduced his Cymbalta doses down to the lowest available dose of 20 mg, after which he stopped taking Cymbalta altogether. While reducing his dose and upon completely stopping Cymbalta, Plaintiff experienced severe and dangerous withdrawal symptoms. By way of example, Plaintiff experienced brain and body zaps, dizziness, nausea, vomiting, muscle spasms and pain, diarrhea, sweating, tremors, heart palpations, and insomnia. In addition, Plaintiff's experience of withdrawal affected his ability to work.

37. At all times relevant, Lilly knew or should have known that Cymbalta was in a defective condition and was and is inherently dangerous and unsafe when used in the manner instructed and provided for by Lilly.

38. At all times relevant, Lilly knew or should have known of the significantly

increased risk of withdrawal symptoms posed by Cymbalta, including their severity and duration, and yet failed to adequately warn about said risks.

39. At all times relevant, Lilly engaged in a willful, wanton, and reckless conduct, including its defective design of Cymbalta and its failure to fully and accurately warn about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms and that the ability to gradually taper was restricted because of Cymbalta's design, all of which induced physicians to prescribe Cymbalta and consumers to use it, including Plaintiff and his physicians.

40. Plaintiff's use of the drug and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to its: failure to warn users and physicians of the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms; provide adequate instructions to users and physicians for stopping Cymbalta; failure to warn that Cymbalta's design severely restricts the ability to taper; and design of the Cymbalta capsules (when first submitted to the FDA) in a way that did not allow for a more gradual taper (reduction in dosage).

41. If Lilly had adequately, accurately and properly warned about the withdrawal risk associated with Cymbalta, including the high risk of experiencing withdrawal symptoms and their frequency and severity, Plaintiff's physician would not have prescribed the drug to Plaintiff; Plaintiff would have refused the drug; and/or Plaintiff's physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid Plaintiff's injuries and damages.

42. As a direct and proximate result of taking Cymbalta, Plaintiff suffered compensable injuries, including but not limited to the following:

a. physical, emotional, and psychological injuries;

b. past and future pain and suffering;

c. past and future mental anguish;

d. loss of enjoyment of life; and

e. past and future medical and related expenses.

FIRST CAUSE OF ACTION

NEGLIGENCE

43. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

44. Lilly owed to Plaintiff, and to other consumers and patients, a duty to exercise reasonable care in the design, formulation, manufacture, sale, promotion, supply and/or distribution of the drug Cymbalta, including the duty to assure that the product carries adequate warnings and that the product is not unreasonably dangerous as designed.

45. Lilly was negligent in the design, manufacture, testing, advertising, marketing, promoting, labeling, supply, and sale of Cymbalta in that it:

a. Failed to adequately warn of and affirmatively misrepresented the frequency, severity and/or duration of Cymbalta's withdrawal symptoms;

b. Failed to adequately warn that Cymbalta could cause patients to become physically dependent on Cymbalta;

c. Failed to warn patients and health care professionals that the design of Cymbalta capsules together with the available dosage strengths restrict the ability to taper because the lowest dosage strength available is 20 mg; tapering down to 20 mg can only be done in 10 mg increments; and doses

are in capsules that are not intended to be opened;

d. Misled users by suggesting that Cymbalta withdrawal is rare;

e. Failed to adequately warn that the risks of Cymbalta withdrawal symptoms exceed the risk of withdrawal symptoms posed by alternative treatment options;

f. Negligently designed Cymbalta in a way that it knew would cause withdrawal and physical dependency;

g. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed, material facts regarding the safety of Cymbalta to the Plaintiff, the public, and the medical community;

h. Failed to comply with its post-manufacturing duty to warn that Cymbalta was being promoted, distributed and prescribed without adequate warnings of the true frequency, severity, and/or duration of potential withdrawal symptoms; and

i. Was otherwise careless, negligent, grossly negligent, reckless, and acted with willful, wanton, and intentional disregard for Plaintiff's rights and safety.

46. Despite the fact that Lilly knew, or should have known, that Cymbalta could cause frequent and severe withdrawal symptoms, Lilly continued to market Cymbalta to consumers, including Plaintiff, without adequate warnings about the frequency, severity, and/or duration of the withdrawal symptoms, without information about how to safely taper off the drug, and without warning that the ability to gradually taper was restricted because of Cymbalta's design. Lilly knew, or should have known, that Cymbalta users would suffer

foreseeable injuries as a result of its failure to exercise ordinary care, as described above. Lilly knew or should have known that the Cymbalta designed, formulated, manufactured, and/or supplied by it was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

47. Had Lilly provided instructions for the proper method for stopping Cymbalta and/or adequate warnings regarding the frequency and severity of the withdrawal and dependency risks and that the ability to gradually taper was restricted because of Cymbalta's design, Plaintiff's injuries would have been avoided.

48. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

49. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION

STRICT PRODUCT LIABILITY – DESIGN DEFECT

50. Plaintiff incorporates by reference, as if fully set forth herein, all other

paragraphs of this Complaint.

51. At all times relevant, Lilly was engaged in the business of selling Cymbalta in the State of Wisconsin.

52. The Cymbalta manufactured, marketed, promoted and sold by Lilly was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

53. Lilly introduced a product into the stream of commerce that is defective in design, in that the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by Lilly, and Lilly's omission of the alternative design renders the product unreasonably dangerous. The harm of Cymbalta's design outweighs and benefit derived therefrom. The unreasonably dangerous nature of Cymbalta caused serious harm to Plaintiff.

54. Lilly manufactured, marketed, promoted and sold a product that was merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

55. Lilly placed Cymbalta into the stream of commerce with wanton and reckless disregard for public safety. Cymbalta's elevated risk of withdrawal was not obvious, nor was it common knowledge.

56. Despite evidence that Cymbalta is dangerous and likely to place users at serious risk to their health, Lilly failed to disclose and warn of the health hazards and risks associated with Cymbalta and, in fact, acted to deceive the medical community and public at large, including all potential users of Cymbalta, by promoting it as safe.

57. Lilly knew or should have known that physicians and other healthcare providers

began commonly prescribing Cymbalta as a safe product despite the fact that the design of Cymbalta pills, as delayed-release capsules of beads at 20, 30 and 60 mg doses only, along with the instruction to swallow them whole, prevents users from being able to gradually taper off Cymbalta beyond the 20 mg dose or at increments more gradual than 10 mg. Cymbalta users such as Plaintiff are thus unable to avoid the danger of Lilly's design upon cessation of treatment. Moreover, Lilly knew that the likelihood of experiencing withdrawal symptoms (such that gradual tapering would be required) is significant.

58. Lilly could have originally employed a reasonable alternative design prior to FDA approval that would have allowed users to taper gradually and thus lessen the risk of injury. The risk of harm inherent in Lilly's design of Cymbalta capsules outweighs the utility of its design. There are other antidepressant medications and similar drugs on the market with safer alternative designs, with respect to patients' and physicians' ability to gradually decrease the dosage, such as scored tablets that can more easily be halved and quartered. *See Estate of Cassel v. Alza Corp.*, No. 12-cv-771-WMC, 2014 WL 856023 (Mar. 5, 2014 W.D. Wis.) (dismissing drug manufacturer's motions for summary judgment and judgment as a matter of law where defendant offered no evidence that the FDA would have prohibited drug manufacturer from submitting a safer and reasonable alternative design in compliance with state law).

59. As a direct and proximate result of Lilly's widespread promotional activity, physicians commonly prescribe Cymbalta as safe.

60. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue

to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

61. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory and statutory damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION

STRICT PRODUCT LIABILITY – FAILURE TO WARN

62. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

63. Lilly researched, tested, developed, designed, licensed, manufactured, packaged, inspected, labeled, distributed, sold, marketed, promoted and/or introduced Cymbalta into the stream of commerce and in the course of same, directly advertised and/or marketed Cymbalta to consumers or persons responsible for consumers, and therefore, had a duty to warn Plaintiff and Plaintiff's physicians of the risks associated with stopping Cymbalta, which Lilly knew or should have known are inherent in the use of Cymbalta.

64. Lilly had a duty to warn users and physicians fully and accurately of the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms, which it knew or should have known, can be caused by the discontinuation of Cymbalta and/or are associated with Cymbalta discontinuation, including brain and body zaps, dizziness, nausea, vomiting, muscle spasms and pain, diarrhea, sweating, tremors, heart palpations, and insomnia .

65. Furthermore, Lilly had a duty to provide users and physicians with adequate

instructions for stopping Cymbalta. Lilly failed to provide users and physicians with instructions or guidelines regarding a tapering regimen. Moreover, Lilly had a duty to warn users and physicians that the design of Cymbalta severely restricts the ability to gradually taper off the drug.

66. Cymbalta was under the exclusive control of Lilly and was not accompanied by appropriate warnings regarding the frequency, severity, and duration of possible adverse side effects and complications associated with the discontinuation of Cymbalta. The information given to consumers and physicians did not accurately reflect the risk, incidence, scope or severity of such withdrawal symptoms to the consumer as compared to other similar products available in the market, which possessed lower risk of such symptoms. The promotional activities of Lilly further diluted and/or minimized any warnings that were provided with the product.

67. Lilly downplayed the serious and dangerous risk of withdrawal of Cymbalta in order to foster and heighten sales of the product.

68. Cymbalta was defective and unreasonably dangerous when it left the possession of Lilly in that it contained instructions insufficient to fully inform users and physicians on how to stop Cymbalta and warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including but not limited to severe, debilitating withdrawal symptoms and the inability to effectively taper off the medication due to its design. Even though Lilly knew or should have known the risks associated with Cymbalta, it failed to provide adequate warnings.

69. The foreseeable risks of withdrawal-related harm posed by Cymbalta could have been reduced or avoided by the provision of reasonable instructions or warnings by Lilly. Lilly's omission of reasonable instructions or warnings rendered Cymbalta not reasonably safe.

70. Plaintiff used Cymbalta as intended or in a reasonably foreseeable manner.

71. Plaintiff could not have discovered any defect in the drug through the exercise of reasonable care.

72. Lilly, as manufacturer of Cymbalta and other pharmaceutical prescription drugs, is held to the level of knowledge of an expert in the field, and further, Lilly had knowledge of the dangerous risks of Cymbalta withdrawal.

73. Plaintiff did not have the same knowledge as Lilly and no adequate warning was communicated to his physicians.

74. Lilly had a continuing duty to warn consumers and the medical community, including Plaintiff and his physicians, of the dangers associated with Cymbalta. By negligently and wantonly failing to adequately warn of the dangers associated with the use of Cymbalta, Lilly breached its duty.

75. Although Lilly knew or should have known of the defective nature of Cymbalta, it continued to design, manufacture, market and sell the drug without providing adequate warnings or instructions concerning the use of the drug in order to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harms posed by the drug.

76. In addition, Lilly's conduct in the packaging, warning, marketing, advertising, promoting, distribution, and sale of the drug was committed with knowing, conscious, willful, wanton, intentional, and deliberate disregard for the value of human life, and the rights and safety of consumers, including Plaintiff.

77. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred

and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

78. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION

STRICT PRODUCT LIABILITY

79. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

80. Lilly designed, manufactured, marketed, promoted, sold, supplied, and/or distributed Cymbalta in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

81. Lilly designed, manufactured, marketed, promoted, sold, supplied, and/or distributed Cymbalta, which was expected to and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Lilly.

82. Plaintiff used Cymbalta as prescribed and in a manner normally intended, recommended, promoted, and marketed by Lilly.

83. Cymbalta failed to perform safely when used by ordinary consumers, including Plaintiff, when used as intended and in a reasonably foreseeable manner.

84. Cymbalta was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design and formulation.

85. Cymbalta was defective in design or formulation in that it posed a greater likelihood of injury compared to other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

86. Cymbalta was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with, nor was otherwise accompanied by, warnings adequate to alert consumers, including Plaintiff and his physicians, of the risks described herein, including the significant increased risk of withdrawal symptoms and the inability to effectively taper off the medication due to its design.

87. Although Lilly knew or should have known of the defective nature of Cymbalta, it continued to design, manufacture, market, and sell Cymbalta in order to maximize sales and profits at the expense of the public health and safety. By so acting, Lilly acted with a conscious and deliberate disregard of the foreseeable harm caused by Cymbalta.

88. Plaintiff could not, through the exercise of reasonable care, have discovered Cymbalta's defects or perceived the dangers posed by the drug.

89. Lilly's conduct as described herein was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Lilly and deter it from similar conduct in the future.

90. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress,

sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

91. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

92. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

93. Lilly owed a duty to Plaintiff and his physicians to convey and communicate truthful and accurate information about Cymbalta.

94. Lilly represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal side effects were no different, no worse and no more frequent, than other similar products in the market. These representations were, in fact, false.

95. Lilly was negligent in failing to exercise due care in making the aforesaid representations.

96. Lilly had a pecuniary interest in making said representations, which were made in order to expand sales and increase revenue Cymbalta.

97. At the time said representations were made by Lilly, at the time Plaintiff and his

physicians took the actions herein alleged, Plaintiff and his physicians were ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff and his physicians were induced to, and did, use Cymbalta and attempt to discontinue from Cymbalta. If Plaintiff and his physicians had known the actual facts, Plaintiff's injuries would have been avoided because Plaintiff's physician would not have prescribed the drug, Plaintiff would not have taken the drug, and/or the risk would have been conveyed to Plaintiff in a way so as to alter the prescription and avoid Plaintiff's injuries.

98. The reliance of Plaintiff and his physicians upon Lilly's representations was justified because the representations were made by individuals and entities that appeared to be in a position to know the true facts relating to risks associated with Cymbalta.

99. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered pecuniary losses including but not limited to past and future medical and related expenses.

100. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory and statutory damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION

FRAUD

101. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

102. Lilly committed fraud by actively concealing material adverse information that was in its possession from its labeling and marketing of Cymbalta, including but not limited to, concealing the true frequency, severity and duration of Cymbalta's withdrawal side effects, and

by falsely representing the withdrawal risk associated with Cymbalta, including the failure to inform that effective tapering was not possible due to the design of its dosage and delivery system.

103. Lilly represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal side effects were no different, and no worse and no more frequent, than other similar products in the market. These representations were, in fact, false and material.

104. The specific acts of Lilly include the following:

a. Fraudulently suggesting that the withdrawal risk is rare, or occurred at a rate of approximately one (1) percent, when the overall rate of patients experiencing withdrawal, according to Lilly's own clinical trials, is high (at least 44.3% to 50%). Furthermore, an analysis of the data from Lilly's clinical trials reveals, with statistically significant results, that in comparison to stopping a placebo, stopping Cymbalta elevated the risk of specific withdrawal symptoms as much as 23-fold (i.e., nausea 23-fold, dizziness 17-fold, paresthesia 11-fold, irritability 9-fold, nightmares 8-fold, headaches 7-fold, and vomiting 4-fold);

b. Fraudulently omitting material information in its labeling and marketing concerning the severity of Cymbalta withdrawal including the fact that, in Lilly's clinical trials, between 9.6% and 17.2% suffered severe withdrawal (approximately 50% suffered moderate withdrawal);

c. Fraudulently omitting material information in its labeling and marketing concerning the duration of Cymbalta withdrawal. In fact, more than 50% of patients in the Cymbalta clinical trials continued to suffer from withdrawal symptoms two weeks after coming off the drug. Lilly did not monitor withdrawal beyond two weeks. Lilly was well aware that withdrawal symptoms could be protracted. For instance, the Cymbalta Summary of Product Characteristics" (SmPC) in Europe stated that, "in some individuals [withdrawal symptoms] may be prolonged (2-3 months or more)." The Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition, published in 2010 (in which at least three Lilly consultants were on the working group and review panel) states under "Discontinuation syndrome" that "some patients do experience **more protracted** discontinuation syndromes, particularly those treated with paroxetine [Paxil]" and "as with SSRIs, abrupt discontinuation of SNRIs should be avoided whenever possible. Discontinuation symptoms, **which are sometimes protracted**, are more likely to occur with venlafaxine [Effexor] (and, by implication devenlafaxine [Pristiq]) than duloxetine [Cymbalta] (100) and may necessitate a slower downward titration regimen or change to fluoxetine." Given that Cymbalta's half-life falls between

Effexor's and Paxil's – Effexor having the shortest, Cymbalta the second and Paxil the third – the Guideline is artfully worded;

d. Lilly obscured Cymbalta's true withdrawal risks by deflecting attention away from the Cymbalta-specific clinical trial data showing a clear and significant risk and focusing instead on other SSRIs and SNRIs. For instance, Lilly's label stated "During marketing of other SSRIs and SNRIs … there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt …" Lilly's use of "spontaneous" reports from "other SSRIs or SNRIs" is misleading given that approximately 40% to 50% of patients in Lilly's own clinical trials of Cymbalta reported adverse events. In using this language, Lilly misleadingly suggests that the withdrawal risks associated with other SSRIs and SNRIs are worse than Cymbalta's risks, which is the opposite of the truth – Cymbalta is one of the worst.

e. Lilly obscured Cymbalta's true withdrawal risks by omitting any mention of the fact that the design of its delivery system made effective tapering off of it impossible due to its extremely short half life.

105. Lilly made the aforesaid representations knowingly and/or with reckless disregard for their truth or falsity.

106. Lilly made the aforesaid representations with the intent that Plaintiff and his physicians act upon said representations.

107. At the time said representations were made by Lilly, at the time Plaintiff and his physicians took the actions herein alleged, Plaintiff and his physicians were ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff and his physicians were induced to, and did, use Cymbalta and attempt to discontinue from Cymbalta. If Plaintiff and his physicians had known the actual facts, Plaintiff's injuries would have avoided because either Plaintiff's physician would not have prescribed the drug, Plaintiff would not have taken the drug, and/or the risk would have been conveyed to Plaintiff in a way so as to alter the prescription and avoid Plaintiff's injuries.

108. The reliance of Plaintiff and his physicians upon Lilly's representations was justified because the representations were made by individuals and entities who appeared to

be in a position to know the true facts relating to risks associated with Cymbalta.

109. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

110. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory and statutory damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

111. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

112. As described herein, Plaintiff suffered injuries as a direct and proximate result of his use and discontinuation of Cymbalta.

113. At the time of Plaintiff's use of Cymbalta and resulting injuries, the Cymbalta he was taking was in essentially the same condition as when it left the control and possession of Lilly.

114. At all times relevant, the Cymbalta received and used by Plaintiff was not fit for the ordinary purposes for which it is intended to be used in that, *inter alia*, it posed a higher

risk of withdrawal symptoms – of greater duration and severity – than other similar products available in the market.

115. Plaintiff's injuries were due to the fact that Cymbalta was in a defective condition, as described herein, rendering it unreasonably dangerous to him.

116. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

117. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory and statutory damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate.

PRAYER FOR RELIEF

118. WHEREFORE, Plaintiff respectfully prays for judgment against Lilly as follows:

a. Judgment in favor of Plaintiff and against Lilly, for all damages in such amounts as may be proven at trial;

b. Compensation for economic and non-economic losses, including but not limited to, past and future medical expenses, medical monitoring, out-of-pocket expenses, past and future physical pain and mental anguish, past and future physical impairment, in such amounts as may be proven at trial;

c. Past and future general damages, according to proof;

d. Any future damages resulting from permanent injuries;

e. Compensation for psychological trauma, including but not limited to mental anguish, mental distress, apprehension, anxiety, emotional injury, psychological injury, depression, and aggravation of any pre-existing and/or underlying emotional or mental diseases or conditions;

f. Compensation for pain and suffering;

g. Compensation for loss of enjoyment of life;

h. Punitive and exemplary damages in an amount to be determined by trial;

i. Attorneys' fees and costs;

j. Treble damages;

k. Prejudgment and post-judgment interest;

l. Costs to bring this action; and

Any such other and further relief as the Court may deem just and proper in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff Adam Streeter demands a jury trial.

Respectfully Submitted,

DATED: May 29, 2015

KELLER ROHRBACK L.L.P.

By: /s/ Meredith Gray

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Attorneys for Plaintiff Adam Streeter

CERTIFICATE OF SERVICE

I certify that on May 29, 2015, I electronically filed the foregoing First Corrected Amended Complaint with the Clerk of the Court using the CM/ECF system which shall send electronic notification of such filing to all counsel of record.

/s/ Meredith Gray
Meredith Gray